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IS 12505 (Part 1): 1988 ISO 536611: 1986

# Indian Standard

# TRACHEOSTOMY TUBES

PART 1 CONNECTORS

# भारतीय मानक

दवास नली शाल्य क्रिया नलिकाएं भाग 1 संयोजी

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TRACHEOSTOMY TUBES. PIPE FITTINGS. SPECIFICATIONS

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IS 12505 ( Part 1 ) : 1988

ISO 5366/1:1986

## Indian Standard

# TRACHEOSTOMY TUBES

#### PART 1 CONNECTORS

#### NATIONAL FOREWORD

This Indian Standard (Part 1) which is identical with ISO 5366/1: 1986 'Tracheostomy tubes, Part 1 Connectors', issued by the International Organization for Standardization (ISO), was adopted by the Bureau of Indian Standards on 25 April 1988 on the recommendation of the Anaesthetic, Resuscitation and Allied Equipment Sectional Committee (CPDC 13) and approval of the Consumer Products and Medical Instruments Division Council.

The text of the ISO standard has been approved as suitable for publication as Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.
- b) Comma (, ) has been used as a decimal marker while in Indian Standards the current practice is to use a point (.) as the decimal marker.

This Indian Standard is in two parts. Other part is:

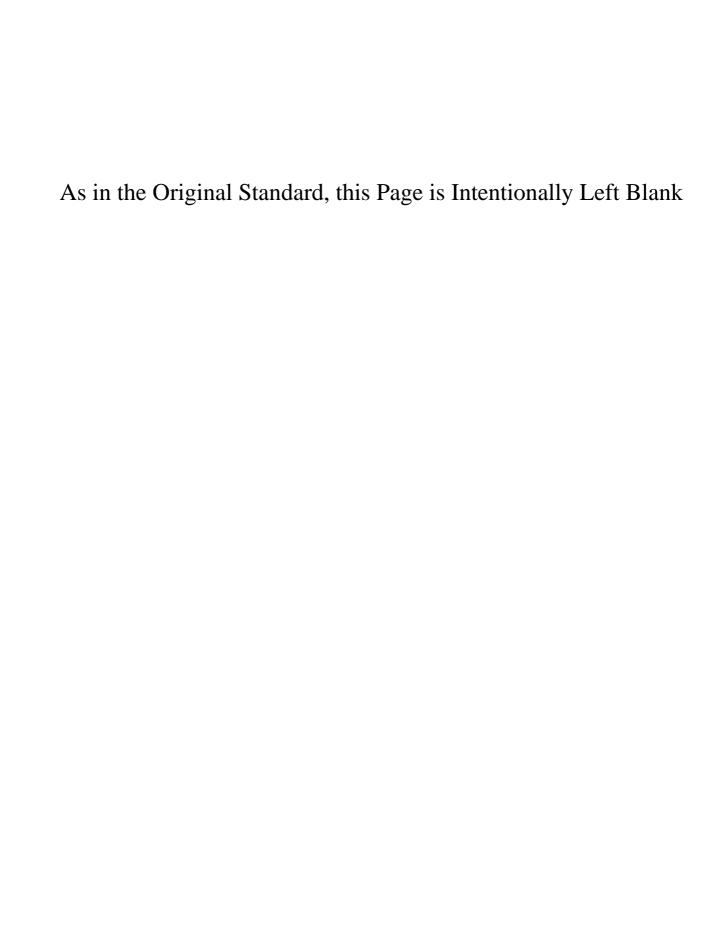
IS 12505 (Part 2): 1988 Tracheostomy tubes: Part 2 Basic requirements (adoption of ISO 5366/2: 1985).

#### **CROSS REFERENCE**

The technical committee responsible for the preparation of this standard has reviewed the provisions of the following ISO standards and has decided that they are acceptable for use in conjunction with this standard:

ISO 5356/1-1987 Anaesthetic and respiratory equipment — Conical connectors, Part 1 Cones and sockets.

ISO 4135-1979 Anaesthesiology - Vocabulary.



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#### 0 Introduction

There an many advantages in harmonizing the requirements for connectors for tracheostomy tubes with those already widely used for tracheal tubes.

The patient connection port of the breathing system of an anaesthetic machine or ventilator is a coaxial **22** mm male/15 mm female conical connector, an important purpose of the smaller connector being to mate with the 15 mm male tracheal tube connector. It Is, therefore, advantageous to use the same size of fitting, for tracheostomy tubes used for patients during surgical operations and for those for whom artificial ventilation or other respiratory support may be required.

Inadvertent disconnection of the breathing system from the tracheostomy tube is a well-recognized hazard and it istherefore specified for the larger sizes of tube (6 mm internal diameter and greater) that the male 15 mm conical fitting shall be permanently attached to the tracheostomy tube.

It is also recommended that the design should permit the fitting of a device to make a more secure attachment between the conical fittings if so desired. Such a device may, however, introduce other hazards such as that of accidental extubation. It should, therefore, be as light and compact as possible with any protuberances designed so as to minimize the likelihood of their catching on attendants, hands, surgical dressings or other equipment.

This International Standard recognizes that a permanently attached conical fitting as specified for the larger tubes may, because of its bulk, prove impracticable for use with infants and small children and that there is a wide variety

of acceptable fittings used in clinical paediatric practice. For these reasons it is not a mandatory requirement that the 15 mm conical fitting be permanently attached to the smaller trackestomy tubes up to and including size 5,5 mm internal diameter. Any other type of connector, however, should either terminate in a 15 mm male conical fitting at its machine end or mate with an adaptor having such a fitting at its machine end.

**NOTE** — ISQ 5366/2 specifier basic requirements for tracheostomy tubes.

### 1 Scope and field of application

This part of **ISO 5366 specifies** basic requirements for connectors for tracheostomy tubes for use on patients undergoing surgical **operations** and/or those for whom **artificial** ventilation or other respiratory support may be required.

#### 2 Reference

**ISO 5356]1.** Breathing attachments for inhalation anaesthetic apparatus, lung ventilators and resuscitators — Part 1: Conical fittings and adaptors for breathing **systems**.<sup>1)</sup>

#### 3 Definitions

For the purpose of this part of **ISO** 5366, the following definitions apply.

3.1 tracheostomy tube ( tracheotomy ): Tube designed for Insertion into the trachea through a tracheostomy ( tracheotomy ).2)

<sup>1)</sup> At present at the stage of draft.

<sup>2)</sup> Definition taken from ISO 4135. Anaesthesiology — Vocabulary.

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#### 3.2 machine end:

- (1) End of the tracheostomy tube which is intended to project from the neck of the patient.
- (2) End of connector or the adaptor intended to mate with the breathing system of an anaesthetic machine or ventilator.
- 4 Connectors for tracheostomy tube of size 6 mm internal diameter and greater
- 4.1 Tracheostomy tubes of size 6 mm internal diameter and greater shall have at the machine end a permanently attached male 15 mm chical fitting in accordance with ISO 5356/1 with the exception that the internal diameter of the conical element shall be not less than the internal diameter of the tube.
- 4.2 Any transition in internal diameter shall be tapered to give an adequate lead-in for passage of a suction catheter.

# 5 Connectors for tracheostomy tube of size 5,5 mm internal diameter and less

**Connectors** for tracheostomy tubes of size **5,5** mm internal diameter and less need not be **rermanently** attached to the tracheostomy **tube** but shall either

a) have at the machine end a 15 mm male conical fitting,

or

b) mate with an adaptor which shall have a 15 mm male conical fitting in accordance with ISO 5356/1 at its machine end.

## 6 Retaining devices

- CIT A retaining or locking device may be incorporated in the design to provide added security of attachment of the conical fittings.
- 6.2 Any projections (for example hooks, liggs or study) should be so designed as to minimize the risk of their catching on surgical dressings or other equipment.

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